Amendments to the Specification

Please replace paragraph 6 with the following paragraph:

[6] A medical device system typically supports a plurality of neurological channels. Each neurological channel may be associated with an electrode and an amplifier that provides an associated signal to a processor to determine information about a seizure of a nervous system disorder. Moreover, interactions between neurological channels often occur, such as with an inducement of artifacts, thus adversely affecting the analysis of the signals in the determination and delivery of a treatment therapy. Consequently, there is a real need to reduce channel interactions in order to enhance seizure analysis and provide more effective treatment therapy.

Please replace paragraph 7 with the following paragraph:

[7] The present invention provides apparatuses and methods that selectively blank a neurological channel of a medical device system in the treatment of a nervous system disorder. According to an aspect of the invention, a selected signal of a selected channel may be blanked if it is determined that the selected signal may be affected by an artifact when the medical device system delivers a treatment therapy. The artifact may be generated by a first electrode that is being stimulated, causing the artifact to be induced on a selected electrode that is associated with the selected signal. In one embodiment, the selected signal may be blanked by hardware, in which the selected electrode is disconnected from the selected channel (which may include ~~an~~ selected amplifier) and is connected to a fixed voltage in order to avoid saturation of the selected amplifier. With another embodiment, the selected channel may be blanked by software, in which a signal processor is instructed not to process neurological data on the selected channel for a determined time duration. Other embodiments may combine hardware and software blanking for the selected signal.

Please replace paragraph 57 with the following paragraph:

[57] Figure 5 is a schematic block diagram depicting the hardware interface processor 205 associated with the bedside device 107. Hardware interface processor 205 comprises a micro controller 503 to control blanking circuitry 301, sense electronics module 201, and stimulation electronics module 203. It also notifies signal processor 207 when data is available for further processing. Hardware interface processor 205, as depicted, further includes a tri-state bus interface 501 that is connected to the sense electronics, a signal processor and the micro-controller 503.

Please replace 61 with the following paragraph:

[61] Figure 8 shows a functional diagram of an example of a seizure detection algorithm 800 that may be used. Generally, the seizure detection algorithm 800 is capable of detecting brain activity changes based on the spectral characteristics, intensity (ratio), spread, and duration of an electrical (EEG, ECoG, and/or EKG) signal 801 that is obtained from a set of electrodes. In the embodiment of external system 100, eight ECoG channels may be supported, although other embodiments may support a different number of channels. The analog EEG or ECoG data from the electrodes 101 are transformed to digital data with an A to D converter in the bedside device 107. In the hybrid system 1000, the A to D converter may be in the implantable device 953. A digital filter such as a finite impulse response (FIR) filter 803 is configured to estimate the power spectrum density characteristics of a set of electrical brain signals. A foreground determinator 805 associates a foreground value of the signals with a moving foreground interval of a predetermined time length (e.g., 2-seconds), which may be programmable. In the embodiment, foreground determinator 805 squares the value of each sample in the foreground interval and selects the median value. A background determinator 807 associates a background value with a moving background interval of predetermined time length (e.g., 30 minutes), which again may be programmable. At any point in time, the current foreground and background values are computed, respectively, from the foreground and background intervals that immediately precede that time point. Background determinator 807 squares the value of each sample in the

background interval and selects the median value. The seizure detection algorithm 800 then processes the results of background determinator 807 through an "exponential forgetting" adjustor 809 that combines the results with previous results from background determinator 807 to produce ~~a~~ an exponentially-smoothed background value. A module 811 then divides the foreground value by the exponentially-smoothed background value to determine a ratio for each signal from each electrode in a selected electrode group. Module 811 also determines the largest ratio from the group of electrodes. The value of the largest ratio is then fed into a detection criterion module 813, which analyzes the sequence of largest ratios to determine when an event is detected. Output 814 from algorithm 800 includes notification that an event has occurred ("detection") as well as variables quantifying the event (e.g., ratio, extent of spread, and duration from all electrodes).

Please replace paragraph 66 with the following paragraph:

[66] An apparatus 1000 (e.g., the external device 950) is powered by a rechargeable/replaceable battery 1025 and is voltage regulated by a voltage regulation circuit 1019. A DSP controller 1005 processes neurological data from implantable device 953 and records/stores processed data in a boot flash memory 1007 or in a compact flash memory 1023, which extends the recording capability of memory 1009 ~~1007~~. The apparatus 1000 may be instructed by a user through buttons 1013. The corresponding inputted information is received by a peripheral interface control (PIC) microprocessor 1011 through a RS232 interface 1017. The user may instruct the DSP controller 1005 to process, store, and retrieve neurological data through PIC microprocessor 1011 ~~1005~~. Also, the user may obtain information (e.g., status and selected processed data) through an LCD screen 1015. The apparatus 1000 further includes speaker 1027 in communication with the ADSP controller 1005.

Please replace paragraph 68 with the following paragraph:

[68] Each electrode of the set of electrodes 1101 may either receive a neurological signal or may stimulate surrounding tissue. Stimulation of any of the electrodes contained in the electrode set 1101 is generated by a stimulation IC 1105, as instructed by a microprocessor 1119. When stimulation is generated through an electrode, the electrode is blanked by a blanking circuit 1107 so that a neurological signal is not received by channel electronics (e.g., amplifier 1111). When microcontroller 1119 determines that a channel shall be able to receive a neurological signal, an analog to digital converter (ADC) 1113 samples the neurological signal at a desired rate (e.g., 250 times per second). The digitized neurological signal may be stored in a waveform memory 1115 so that the neurological data may be retrieved by the apparatus 1000 when instructed via an analog to digital bus 1117. The micro controller 1119 is coupled to a 1 MHz crystal oscillator 1121 and control registers 1109 are coupled to the amplifier 1111, the ADC 1113 and the telemetry transceiver 1127.

Please replace paragraph 69 with the following paragraph:

[69] **IMPLANTED SYSTEM** – Figure 12 shows an embodiment of an implanted system 5 ~~10~~ for treatment of a nervous system disorder in accordance with another embodiment of the invention. As discussed, although the implanted system 5 ~~10~~ is discussed in the context of providing brain stimulation, it will be appreciated that the implanted system 5 ~~10~~ may also be used to provide other treatment therapies at the brain or head or at other locations of the body. The implanted system 5 ~~10~~ generally includes an implanted device 10 ~~20~~ coupled to one or more therapy delivery elements 30. The therapy delivery elements 30, of course, may also serve as monitoring elements to receive a neurological signal. The implanted device 10 ~~20~~ may continuously or intermittently communicate with an external programmer 23 through a coil 24 and wire 21 (e.g., patient or physician programmer) via telemetry using, for example, radio-frequency signals. In this embodiment, each of the features and functionalities discussed herein are provided by the implanted device 10 ~~20~~.

Please replace paragraph 74 with the following paragraph:

Figure 14 discloses one embodiment of such a relaying module in the form of a device that is worn, for example, on the patient's wrist. In such an arrangement, the implanted component 1405 of the medical device system communicates with the relaying module 1415 via telemetry antenna 1410. Similarly, an ~~the~~ external ~~component~~ wearable signal processor 1425 (which may be in bi-directional communication with physician programmer 1435) communicates with the relaying module 1415 via antenna 1420. In the embodiment, a telemetry link 1421 between relaying module 1415 and antenna 1420 comprises a 3 MHz body wave telemetry link. To avoid interference, the relaying module 1415 may communicate with the external and implanted components using differing communication schemes. In some embodiments, the reverse direction and the forward direction of telemetry link 1421 may be associated with different frequency spectra. The relaying module 1415 thereby provides a greater range of communications between components of medical device system. For example, in the embodiment of the implanted system 10, the external programmer 23 may communicate with the implanted device 20 from a more remote location. The external programmer 23 may be across the room and still be in communication via the relaying module 1415. Similarly, in the embodiment of the hybrid system 1000, the external device 950 may be located further away than being worn by the patient. With the telemetry booster stage, the use of hybrid system 1000 is more convenient to the patient in particular at night while sleeping or when taking a shower, eliminating the need for the external device 950 to be worn on the body.

Please replace paragraph 77 with the following paragraph:

[77] Figure 15 shows a top-level flow diagram for a clock synchronization and calibration process 1500. For clarity, the following discussion is provided in the context of the external system 100, although other embodiments are possible. The process starts at step 1502 and in~~In~~ step 1503, a user initiates a study and sets-up the parameters through programmer 109 in step 1505. In the embodiment, the user enters a selected time (through programmer 109) that is different (which may be greater) than the reference time that is associated with monitoring equipment 105. (The reference time may comprise the associated date such month and day.) When the user determines that the time associated with monitoring equipment 105 equals the selected time, the user synchronizes the clocks in step 1507. Consequently, programmer 109 may generate a control message to bedside device 107 to synchronize the clock of bedside device 107. In the embodiment, the user selects an icon; however, other embodiments may use a Global Positioning System (GPS) clock reference or use a control line from monitoring equipment to activate the synchronization of clocks. In step 1509, programmer 109 determines if the clocks of bedside device 107 and programmer 109 were successfully synchronized and notifies the user through a real-time data display of programmer 109. In step 1511, the external system 100 starts run mode operation in which the medical device system may operate its intended functions.

Please replace paragraph 78 with the following paragraph:

[78] During the operation of the external system 100 over time, the clocks of monitoring equipment 105, programmer 109, and bedside device 107 may drift with respect to each other. In the embodiment, the clocks of programmer 109 and bedside device 107 are calibrated using the clock of monitoring equipment 105 as a reference. In step 1513, the programmer 109 notifies the user that calibration should be performed (e.g., every 12 hours, although other time periods may be utilized). The user consequently enters a selected time (through programmer 109) that is greater than the present time that is associated with monitoring equipment 105. When the user determines that the time associated with monitoring equipment 105 equals the selected time, the user calibrates the clocks in step 1513. With the calibration process, the clocks of bedside device 107 and programmer 109 are not modified. Rather a "drift" time (equal to the difference between the clock in bedside device 107 and monitoring equipment 105) is stored to a file. Data that are subsequently collected by bedside device 107 can be correlated to the time of monitoring equipment 105 by adjusting the time of bedside device 107 by the drift time. (In the embodiment, the drift time is determined by the difference between the current time of the second clock and the reference time of the first clock.) However, if the drift time is determined to be greater than a predetermined threshold (e.g., one second) in step 1515, programmer 109 may notify the user that the clocks need to be re-synchronized or more frequently calibrated to accurately track the drift between the clocks. If that is the case, the clocks are synchronized in step 1517. Otherwise, the real-time operation is continued in step 1519.

Please replace paragraph 79 with the following paragraph:

[79] Figure 16 shows specific flow diagrams for clock synchronization and calibration in relation to Figure 15. Starting at step 1600, steps~~Steps~~ 1601-1609 correspond to synchronizing the clocks in the external system 100 as shown in steps 1507 and 1517. Steps 1611-1619 correspond to manually calibrating the clocks as shown in step 1513. Additionally, as shown in steps 1621-1629, the external system 100 may periodically (e.g., every 10 minutes) calibrate the clocks of the programmer 109 and bedside device 107 without requiring intervention by the user.

In step 1623, programmer 109 retrieves the time from bedside device 107. Programmer 109 compares its time with the retrieved time from bedside device 107 and calculates an updated drift time. Programmer 109 stores the adjusted drift time for correlating times subsequently. As discussed, synchronization may also be utilized in either the hybrid or implanted systems. For example, in the embodiment of the implanted system, the implanted device may provide to or receive from an external component (e.g., patient or physician programmer, video equipment, testing equipment) a clock synchronization/calibration signal, and the calibration/synchronization techniques discussed herein may be utilized to correspond the implanted device with the one or more external devices. Moreover, the clock reference (i.e., the reference clock to which all other clocks would be synchronized/calibrated) may be the clock in the implanted component, one of the external components, a GPS clock, an atomic clock, or any other reference clock.

Please replace paragraph 89 with the following paragraph:

[89] As another example, a neurological signal parameter that may be monitored for signal quality is a "mains" artifact, namely an excessive noise at a certain frequency, for example, approximately 60 Hz. Such a signal may be indicative of outside noise interference (e.g., caused by turning on a light bulb ~~lightbulb~~) and may be indicative of a faulty or high-impedance electrode. Of course, the frequency may vary. For example, in European countries, the AC noise interference has a frequency of approximately 50Hz. The medical device system may measure instantaneous amplitudes of the signal and calculate a running average for a given moving window, of 60 seconds duration. Once it is determined that the average frequency or amplitude of the signal is excessive, namely above a predetermined threshold, the medical device can remove the associated electrode from consideration in the data analysis process (e.g., a seizure detection algorithm). Once the average frequency or amplitude of the signal returns below a second (typically lower) predetermined level, the associated electrode may then be brought back into consideration.

Please replace paragraph 98 with the following paragraph:

[98] A maximal amount of poor quality data that is tolerable may be qualified using different criterion. Poor quality data may be gauged by a signal power to noise power ratio (S/N) that is associated with neurological data. Also, poor quality data may be gauged by a fraction of the foreground window that contains a noisy signal. Typically, the foreground window is more vulnerable to noise than the background window since the foreground is determined over a shorter time duration. One may also consider different artifacts. Movement artifacts may be detected with accelerometers, in which corresponding outputs may be used to reduce or even cancel the movement artifacts. Other types of artifacts that may be considered include EKG artifacts and disconnection artifacts. EKG artifacts, when recorded from intracranial electrodes, are an indication of high impedance. Disconnection artifacts may be identified by stationary noise in one lead or a set of leads. The characteristics of a baseline that are associated with neurological data may assist in identifying a cause of poor quality data. For example, a flat line without a shift in the baseline and without noise may be indicative that an amplifier has been deactivated or has failed.

Please replace paragraph 101 with the following paragraph:

[101] A time event 1907 corresponds to a clinical behavior onset time (CBOT), in which a patient manifests the symptoms of the neurological event (such as demonstrating the physical characteristics of a seizure). (In some cases, the patient may not manifest the symptoms even though an ITEO occurs.) Typically, if monitoring elements (such as electrodes) are appropriately positioned, the CBOT will occur after the ITEO. However, if the electrodes are placed away from a point of the neurological event, the CBOT may occur before the ITEO because of a delay of the neurological signals propagating through different portions of the patient's brain. A time event 1909 corresponds to an investigator seizure electrographic termination time, in which the electrographic activity sufficiently decreases after a clinical seizure duration 1911.

Please replace paragraph 102 with the following paragraph:

[102] To illustrate an embodiment of a screening procedure for a particular nervous system disorder, Figures 20 and 21 show flow diagrams for a seizure screening process to define treatment therapy according to an embodiment of the invention. Process 2000 comprises a baseline algorithm monitoring sub-process 2003 (comprising steps 2005-2049) and a trial screening sub-process 2151 (comprising steps 2153-2179). The process starts at step 2001 and in~~In~~ step 2002, a physician implants electrodes into a patient in order to conduct process 2000.

Please replace paragraph 105 with the following paragraph:

[105] In step 2027, which comprises sub-steps 2029 and 2031, the correctness of electrode placement for seizure detection is verified. In sub-step 2029, the ITEO (investigator time of electrographic onset corresponding to time event 1903 in Figure 19) and the CBOT (clinical behavior onset time corresponding to time event 1907 in Figure 19) are provided to the medical device system. (In the embodiment, step 2027 is optional so that the clinician need not provide ITEO and CBOT to the medical device system.) In sub-step 2031, the medical device system determines if the ITEO did not occur after the CBOT. In the embodiment, the fact that the CBOT occurs before the ITEO is indicative that the selected electrodes are not sufficiently near the focus. In such a case, step 2032 determines whether to stop screening. If so, screening is ended in step 2034. Otherwise, step 2004 allows the physician ~~physcian~~ to reposition subdural and/or DBS electrodes. The baseline algorithm monitoring sub-process 2003 is repeated.

Please replace paragraph 118 with the following paragraph:

[118] The medical device system may also ensure other efficacy ~~criterion~~ criteria are satisfied for any user-defined treatment therapy configuration. For example, the medical device system providing stimulation therapy may ensure that the polarities of the stimulation pulses are properly defined, e.g., all polarities cannot be off and that the voltage level is greater than zero on at least one stimulation channel, and that at least one cathode and at least one anode are configured.

Please replace paragraph 177 with the following paragraph:

[177] Hardware and /or software blanking may be automatically applied based upon the results of applying signal quality control algorithms, such as those described above, to test the reliability of sensor signals. Application of signal quality control may at anytime result in continuous hardware or software blanking of a particular sensor due to artifact. However, signal quality control algorithms may also be applied to any of the sensor channels to determine if the applied therapy (e.g., stimulation) is causing artifacts that require hardware or software blanking during and after application of the therapy. Those sensor channels determined not to be affected by the application of the treatment therapy do not need to be blanked, thus enhancing the ability of the system to monitor the patient. In addition, periodic checking of a sensor channel following a treatment pulse and applying signal quality algorithms can automatically determine the length of time needed for hardware and/or software blanking for that channel during future applications of the therapy. For example, a signal that is associated with an electrode in proximity of a stimulated electrode may be analyzed to have artifact characteristics, including during a time interval in which an artifact affects the signal. Alternatively, parameters of the therapy treatment may be adjusted within a range of values known to be therapeutic in an effort to reduce the effect on the signal quality of adjacent sensors. In this manner the medical device system can enhance its ~~it's~~ ability to collect data while providing treatment therapy.